510(k) Summary
510(k) Number K110518

JUN 24 2011

Future Path Medical, LLC
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Date Prepared: April 18, 2011
Contact: Ty Bryant, Chairman

1. **Identification of the Device:**
   Proprietary-Trade Name: iBag™ Urine Management System
   Device: Urinometer, electrical
   Regulation Description: Urine flow or volume measuring system.
   Regulation Medical Specialty: Gastroenterology/Urology
   Review Panel: Gastroenterology/Urology
   Product Code: EXS
   Submission Type: 510(K) Exempt subject to 21CFR876.9
   Regulation Number: 876.1800
   Device Class: 2

2. **Equivalent legally marketed devices**: BARD CritiCore (K924436) Bard Urological 510(k): UROTRACK II Monitoring System

3. **Indications for Use (intended use)**. This device is intended to measure/ display collected urine volume. It detects fill level and temperature.

4. **Description of the Device**: iBag™ is a urine management system that includes bladder and temperature measurement for catheterized patients who desire to be fully mobile. iBag™ provides accurate, real-time assistive data. It does this through use of a calibrated drainage bag integrated with a Future Path Medical sensor, a base transmitter unit called Wi-Mitter™ for wireless transmission of urine bag fill and bladder temperature information. Once the Wi-Mitter™ is snapped in place, the container is polled and the measurement of fluid level begins and this data is then transmitted to the patient, the care provider (an aid) a family member, or even to the hospital's base station. Data is transmitted via traditional data networking and may be interpreted and displayed on a user's laptop computer, and other types monitors. Since the data from the Wi-Mitter™ is time and date stamped, time of fill level may be automatically calculated, noted and threshold values used for fill level alarming.
   Features:
   - Automatically measures and displays urine fill level and bladder temperature.
   - Re-usable wireless transmitter is inexpensive and has a one-year battery life
   - Performs functions such as email or text alerts on fill levels.
   - Software is designed to be used with little or no training.
   - Transmits data in real time.

5. **Safety and Effectiveness, Summary of Testing and Comparison to Predicate Device.** Bench and test laboratory results indicate that the new device is as safe and effective as the predicate device. The following testing has been successfully conducted:

- Electrical Safety to IEC 60601-1
- Electromagnetic Compatibility to IEC 60601-1-2
- FCC Compliance Testing
- RF Dosimetric Assessment Testing
- Transmitter effective range.
- User Feedback Study
- Fill level accuracy
- Temperature measurement accuracy
- Battery life computations
- Simulated Use Testing
- Leak Testing
- Sterility Testing

6. Substantial Equivalence Chart

Characteristic	BARD CritiCore (K924436) Bard Urological 510(k): UROTRACK II Monitoring System	iBag™ Urine Management System
Intended Use:	This device is intended to measure/ display collected urine volume. It detects fill level and temperature.	SAME
Configuration	Portable unit with integrated display	Wireless communication (418 mHz) to Netbook type PC via USB
Power Source	6 "D" cell alkaline batteries	3 volt coin-cell size, lithium battery. (e.g., CR2032); 120 VAC for the Netbook display unit.
Urine Bag Capacity	0-2100 ml	1000 and 2000 ml
Volume Accuracy	Not stated	±5% of the actual fill for 70 – 100% fill level readings.
Temperature	50°F to 110°F (l0°C to 43.3°C)	Bladder core temperature is measured in degrees Fahrenheit, °F, units from 50 to 110 °F in increments of 0.1 °F.
Temperature accuracy	± 0.2 °F.	Temperature measurement accuracy is ± 0.2 °F.
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME

7. Conclusion

After analyzing bench, simulated use, and compliance to standards testing using external laboratory testing to applicable standards, it is the conclusion of Future Path LLC that the iBag™ Urine Management System is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Future Path Medical, LLC
c/o Daniel Kamm, P.E.
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JUN 24 2011

Re: K110518
Trade/Device Name: iBag™ Urine Management System
Regulation Number: 21 CFR §876.5250
Regulation Name: Urine Collector and Accessories
Regulatory Class: Class II
Product Code: KNX and EXS
Dated: June 12, 2011
Received: June 16, 2011

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110518

Device Name: iBag™ Urine Management System

Indications For Use:
This device is intended to measure/ display collected urine volume. It detects fill level and temperature.

Prescription Use X AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110518